REMARKS/ARGUMENTS

In order to reduce and simplify the number of issues under consideration in this case and to make a bona fide attempt to clearly place the application in condition for allowance without appeal, all the claims in the application have been canceled except those directed to the specific method of placing the float within the IV bag. Those remaining method claims have also been amended to better delineate the various steps that are utilized in such procedures and to more specifically define the structural/spacial relationship between the separable portion of the cannula assembly and the barrier seal which, in part, enables the novel procedure of the invention to be carried out. Antecedent support has been added to the Specification with regard to the inserted claim language to the opposed faces of the barrier seal (stopper) as well as the interface between the separable portion and the tube upper end in added Claims 22 - 25.

The claims previously presented were rejected over the combination of Walker in view of Davis et al. Walker shows a bag of a two-bag system for blood provided with what is, in effect, an in situ valve that can be broken to allow fluid to flow from a storage bag to a dispensing bag. The

Examiner indicates that separation of an integral unit into two parts as well as two tube portions is an obvious variation—this position is not believed warranted with regard to the present claims as such recite positive and active movement of a portion of a tube connector positioned initially outside the bag thereinto and then removed so as to provide a float. The two bags of Walker are not equivalent to the single bag and separate injector system of applicant, and the applicant's invention does not utilize two tube portions in the sense of the Walker invention.

Walker obviously does not show the method claimed by the claims at bar; and in an attempt to bolster this deficiency, Davis et al has been newly cited. Davis et al does not, however, show or suggest an important part of applicant's invention—that of penetrating the barrier seal with the separable part of the cannula upper end disposed entirely within the bag. The language to accomplish this result has been revised in the newly added and amended claims to set forth a barrier seal with an outer face and an inner face to emphasize that the seal has a significant thickness and so as to provide a positive location (the plane of the inner face) past which the separable part of the cannula upper end is positioned such that it may be actively removed and then serve as the intended float mechanism.

Davis et al, however, does not disclose a needle or spike tip that enters the container in the sense that applicant's cannula upper end separable portion does—all that Davis et al shows is penetrating a container seal such that the contents of the additive container can be aspirated into the delivery container either by vacuum either already present or by pumping the other end of the delivery container. See also the care that Davis et al calls for when the needle (spike) is utilized in this manner to prevent the needle (spike) from fracturing (Column 1, Lines 62 - 67 and Column 5, Lines 19 - 41). The other manner of use that Davis et al utilizes is that of forcing the spike into the seal and then breaking off the tip (the tip stays lodged in the seal) so that the broken off portion forms a receiving area for a luer tip syringe. Obviously for this second alternative to make sense operationally, the broken off area cannot be positioned on the interior side of the container seal as called for in the claims at bar.

Thus in neither of the alternate operational modes described by Davis et al does the removable portion of the cannula upper end pass entirely through the seal and in no instance is the separable portion removed(separated) inside the container (bag) and certainly there is no mention of separating a portion that is frictionally retained on another part. For the Examiner to state that it would have been obvious for one with ordinary skill to provide a piercing

member to allow the connector to breach the seal as taught by Davis et al misses the point since applicant's invention does not simply " breach the seal". Applicant's invention passes the removable portion entirely past the seal to position the removable portion essentially entirely within the container and then manipulates the thus positioned removable portion free from the rest of the cannula upper end so that the removable portion floats free on the surface of the liquid within the bag. Therefore, the combination of Walker in view of Davis et al fails to disclose applicant's invention. In addition, it is believed that within the context of this invention—that of moving the separable portion of a cannula end, then removing it to serve as a safety indicator float—that no prior art exists which either singly or in combination with Walker would anticipate the subject claims.

Applicant's invention is not simply a recognition of something inherent in the prior art—it is a well thought out and specific system set forth in sequential steps which achieves a previously unrecognized result by a different and believed clearly unobvious method and thus is believed patentable.

It is, therefore, believed that all claims as presently written are in a form ready for allowance; however, should claim language modification occur to

the Examiner, such would be welcomed to advance this application. Allowance of Claims 14, 17 – 19 and 22 – 25 at bar in this application is urged.

Respectfully submitted,

Robert J. Doherty
Reg. No. 20,272

Attorney:
Robert J. Doherty, Esquire
11 George Street
Barrington, Rhode Island 02806-1719
Tel. 401/431-1320